

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET
P.O. BOX 1347
WILMINGTON, DELAWARE 19899-1347

—
(302) 658-9200
(302) 658-3989 FAX

MICHAEL J. FLYNN
(302) 351-9661
mflynn@morrisnichols.com

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The Honorable Richard G. Andrews
United States District Court
for the District of Delaware
844 N. King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

REDACTED – PUBLIC VERSION

Re: United Therapeutics Corp v. Liquidia Techs., Inc., C.A. No. 23-975-RGA

Dear Judge Andrews:

At the April 23, 2024 hearing regarding Plaintiff United Therapeutics Corporation’s (UTC) Motion for Preliminary Injunction (D.I. 25), the Court requested that the parties each provide by Friday, April 26, 2024 a proposed bond amount in the event the Court grants UTC’s requested injunction enjoining Defendant Liquidia Technologies, Inc. (Liquidia) from launching its Yutrepla product for the PH-ILD indication. *See Hr’g Tr. at 79:8-17.* The Court further requested that the parties each provide “something that explains why you come up with that number[.]” *Hr’g Tr. at 80:19-81:1.*

Federal Rule of Procedure 65(c) provides that “[t]he court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.” The Third Circuit has long held that while the posting of bond is typically required except in rare circumstances not relevant here, “the amount of the bond is left to the discretion of the court[.]” *Zambelli Fireworks Mfg. Co., Inc. v. Wood*, 592 F.3d 412, 426 (3d Cir. 2010) (quoting *Frank’s GMC Truck Center, Inc. v. General Motors Corp.*, 847 F.2d 100, 103 (3d Cir. 1988)). This Court has previously exercised its discretion to require that bonds be posted in reasonable amounts. *Sensus USA, Inc. v. Franklin*, No. CV 15-742-RGA, 2016 WL 1466488, at *9 (D. Del. Apr. 14, 2016) (granting preliminary injunction, stating “the court is free to exercise its discretion over the amount it deems proper under the rule,” and requiring only that “a reasonable amount” of \$250,000 be posted); *see also U.S. Bank Nat. Ass’n v. Gunn*, No. CIV. 11-1155-RGA, 2012 WL 899550, at *6 (D. Del. Mar. 16, 2012) (requiring only “nominal bond of \$500” because the court found “this amount will protect the parties’ respective interests.”).

Liquidia has not produced any documents in this matter regarding its anticipated launch plan, Yutrepla pricing, discounts, marketing strategy, or expected market share. To UTC’s present awareness, Liquidia also has not engaged in press releases or marketing detailing its expected price for Yutrepla, market share, or costs of goods sold. Accordingly, UTC’s estimates are based on the

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information available to UTC for its own product and reasonable anticipation of how a competitor in this scenario would likely enter and compete, including analogous pharmaceutical markets.

UTC proposes that the Court set the bond at \$110 million. As detailed below, this amount is more than sufficient to protect Liquidia's interests in the event that Liquidia is later determined to have been wrongfully enjoined.

In assessing what amount might reasonably be required to secure Liquidia's lost profits in the event that Liquidia were later determined to be wrongfully enjoined, UTC has sought to assess Liquidia's maximum potential lost profits if it were permitted to launch on the PH-ILD indication. UTC assumes that if Liquidia were permitted to launch on both the PAH and PH-ILD indications there would be significant price competition with UTC's Tyvaso products. Liquidia would likely enter the market with a lower list price than UTC's Tyvaso DPI product to signal its willingness to compete, and the ultimate net price would reflect discounts and rebates to payors of an average of [REDACTED] off of Liquidia's list price, blending the discounts that UTC understands Liquidia is offering to commercial payors and additional discounts that would be made for Medicare Part D plans. That manner and level of price discounting is in line with what has happened in comparable pharmaceutical markets. UTC has further taken into account Liquidia's anticipated cost of goods sold, UTC's manufacturing costs for Tyvaso products, and the anticipated differences in costs between UTC's ongoing manufacturing arrangements and Liquidia's expected arrangements.

UTC further assumes that if Liquidia were permitted to launch on both indications, its share of the treated patient population would grow between May 2024 and June 2025. However, due to the lack of automatic substitution between Yutrepia and Tyvaso products and based on analogous pharmaceutical markets, UTC assumes that uptake of Yutrepia would not exceed [REDACTED] of the treated patient population in the first year of launch. In addition, Liquidia's share of treated patients would grow gradually over time. Accordingly, the profit that Liquidia might expect to earn from a patient will depend on when that patient begins to take Yutrepia. In order to account for the growth in Liquidia's share of treated patients over time, UTC's analysis averages the share of treated patients across 2024 for that year's calculation and applies the same methodology for 2025, rather than attempt to calculate the total patient share that Liquidia might have in each particular month.

In addition, UTC has not applied a number of real world factors that would naturally reduce the amount of the bond. For example, UTC anticipates that Liquidia will engage in some amount of sales under the federal 340B pricing program, which sales will be made at a price further discounted off of average net prices to other payors. UTC, however, has not sought to factor those 340B reductions into these calculations, consistent with UTC's approach to identify a reasonable maximum potential loss that Liquidia could suffer. Furthermore, Tyvaso is delivered in two methods – a nebulized liquid (i.e. an inhaled mist) and a dry powder inhaled product. During oral argument, Liquidia presented slides identifying the number of Tyvaso ILD patients. Those figures represent the combined potential populations using the nebulized form and the dry powder form. Liquidia's Yutrepia is available only in a dry powder inhaled form. Assuming that the patient population is evenly split between nebulized Tyvaso and the dry powder formulation, the numbers in the table below are therefore double what Liquidia's potential patient population and therefore double Liquidia's expected profits would be. Applying this factor would therefore make the bond half of the amount UTC proposes. Nevertheless, as with the other calculations underlying UTC's

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proposed bond, UTC has sought to make assumptions that seek to identify the maximum reasonable amount for the bond, and therefore has not attempted to disaggregate nebulized patients from the dry powder patient population.

Based on the results of the foregoing price, cost, and share inputs, UTC has applied a discount rate of [REDACTED], which is in line with what industry analysts have used for Liquidia's weighted average cost of capital,¹ to reach its proposed bond amount. A table showing UTC's estimate is shown below.

Metric	2024	2025
Cumulative present value of gross profits (\$MM)	\$ [REDACTED]	\$ 109.62

UTC respectfully submits that its proposed bond amount of \$110 million reflects UTC's best estimate, prepared since the hearing earlier this week, of a reasonable maximum amount that would be proper to protect Liquidia's interests. This amount would be more than sufficient secure Liquidia's potential lost profits to the extent the Court grants an injunction prohibiting Liquidia from launching its Yutreptia product for the PH-ILD indication between now and trial, which is set to begin June 23, 2025 (D.I. 45), and it is later determined that Liquidia was wrongfully enjoined from launching Yutreptia for the PH-ILD indication.

UTC notes that, although LIQ's filing today requests a bond in the amount of \$300 million, the lost profits identified in the bottom row of Liquidia's own spreadsheet attached as Exhibit 1 to their filing total [REDACTED]. As a result, UTC requests that the Court set a bond in the amount of \$110 million, but in any event not more than [REDACTED].

UTC is available at the Court's convenience to answer any further questions concerning the proposed bond amount and basis.

¹ Wells Fargo, "UTHR: LQDA Wins Federal Circuit Case as Expected; Limited Fundamental Impact to UTHR," 12/20/2023, at 2.

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Respectfully submitted,


Michael J. Flynn (#5333)
Counsel for Plaintiff United Therapeutics Corporation

cc: Clerk of the Court
All counsel of record